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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,777	03/09/2004	Eija Pirhonen	01942-00019	1657

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BANNER & WITCOFF, LTD.
28 STATE STREET
28th FLOOR
BOSTON, MA 02109-9601

EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,777	PIRHONEN ET AL.	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-14,21 and 24-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-14,21 and 24-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20051213*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to Amendment filed on December 13, 2005. Claims 1, 2, 5-14, 21, and 24-35 are currently pending and are under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawal of Rejections

3. The rejection of claims 29, 30, 31, and 32 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

4. The rejection of claims 8, and 26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

5. The rejection of claims 1, 2, 5-14, 21, 24, 25, 26, 27, 28, 29, and 31-35 under 35 U.S.C. 103(a) as being unpatentable over Pirhonen et al. (U.S. Patent 6,926,903 B2) in view of Santos, E. et al. (IDS document: AQ; J. Biomed. Mater. Res. 41(1): 87-94 (1998)) is withdrawn.

6. The rejection of claim 30 under 35 U.S.C. 103(a) as being unpatentable over Pirhonen et al. (U.S. Patent 6,926,903 B2) in view of Santos, E. et al. (IDS document: AQ; J. Biomed. Mater. Res. 41(1): 87-94 (1998)) as applied to claims 1, 2, 5-14, 21, 24, 25, 26, 27, 28, 29, and 31-35 above, and further in view of Hall (U.S. Patent 6,730,129 B1) is withdrawn.

New Objections and Rejections

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1, 7, 8, 9, 10, and 25-35 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, and 14 of copending Application No. 10/354,856 (US 2004/0152627 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a genus of the species currently claimed in the pending application. The pharmaceutical composition comprising a pharmaceutically acceptable carrier, a pyrrolidone, wherein the pyrrolidone is selected from the group consisting of 1-methyl-2-pyrrolidone, 1-ethyl-2-pyrrolidone, 2-pyrrolidone, and 1-cyclohexyl-2-pyrrolidone, and a bone morphogenetic protein. The pharmaceutically acceptable carrier can be reasonably interpreted to comprise a porous carrier of ceramic, glass ceramic, or glass, because Weber, F. et al. describes

pharmaceutically acceptable carriers to include a bioglass [0046], and the pharmaceutical composition in the form of an implant [0049]. Bioglass is a glass that contains silicon, calcium, and sodium oxides. The surface is favorable for the re-growth of bone tissue (see Cornell class notes attached for description of bioglass).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 10 recites the limitations "carrier selected from the group consisting of calcium phosphates, hydroxyl apatites, silica gels, anorganic mineral bone matrixes, xerogels, and sol-gel glasses". There is insufficient antecedent basis for this limitation in the claim. Claim 1 describes a porous carrier of ceramic or glass ceramic or glass. How are the members disclosed in claim 10 encompassed by claim 1?

12. Claim 11 recites the limitation "ceramic/polymer composite" in the end of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is not drawn to a composite carrier rather it is drawn to a porous carrier of ceramic or glass ceramic or glass.

13. Claim 12 is rejected for depending on rejected claim 11 and not curing the indefiniteness of claim 11.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

15. Claims 1, 2, 5, 6, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Dieter et al. (U.S. Patent 5,423,919).

Dieter et al. disclose a composition comprising a ceramic particulate spherical or conical in shape in an amount of 1-20 wt % (preferably 5-15%) of the total composition; and a liquid organic solvent in an amount of 80-99 wt % (preferably 85-95%) of the total composition, wherein the ceramic particulate is dispersed within the liquid solvent and wherein the solvent also has present in it N-methyl-2-pyrrolidone in an amount of 1-15 wt % (preferably 3-12%) of the total composition (see Abstract, and col. 4, lines 34-43). The composition is placed in glass tube, and circulated by means of a laboratory circulation system (see col. 5, lines 40-55). If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction (see MPEP 2111.02). The composition disclosed by Dieter et al. encompasses the limitations of the pending claims and therefore anticipates the claims.

16. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Rolle et al. (US Patent 6,969,303 B1).

Rolle et al. disclose a composition comprising calcium phosphate mixed with a solvent in an amount up to about 55% by total weight, wherein said solvent is selected from the group consisting of water, aliphatic hydrocarbons, aromatic hydrocarbons, alcohols, esters, glycol ethers, ketones, chlorinated solvents and glycols (see claim 6). The 1-methyl-2-pyrrolidone is reasonably interpreted to be an aromatic hydrocarbon. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction (see MPEP 2111.02). The composition disclosed by Rolle et al. encompasses the limitations of the pending claim and therefore anticipates the claim.

Claim Rejections - 35 USC § 103

17. Claims 1, 7, 8, 9, 10, and 25-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber, F. (US 2004/0152627 A1).

Weber, F. discloses a pharmaceutical composition comprising a pharmaceutically acceptable carrier, a pyrrolidone, wherein the pyrrolidone is selected from the group consisting of 1-methyl-2-pyrrolidone, 1-ethyl-2-pyrrolidone, 2-pyrrolidone, and 1-cyclohexyl-2-pyrrolidone, and a bone morphogenetic protein (see entire document, particularly claims 1, 4,

and 14). The pharmaceutically acceptable carrier can be reasonably interpreted to comprise a porous carrier of ceramic, glass ceramic, or glass, because Weber, F. et al. describes pharmaceutically acceptable carriers to include bioglass [0046], and the pharmaceutical composition in the form of an implant [0049]. Bioglass is a glass ceramic that contains silicon, calcium, and sodium oxides. The surface is favorable for the re-growth of bone tissue (see Cornell class notes attached for description of bioglass).

A person having ordinary skill in the art would have expected to succeed in using a composition comprising 1-methyl-2-pyrrolidone, and bone morphogenetic protein, along with a porous carrier of glass ceramic, because each material has been used for induction of bone formation, and Weber, F. et al. describes the pharmaceutically acceptable carrier to include a bioglass, which is a glass ceramic. Therefore, it would have been obvious to the person having ordinary skill in the art to manufacture an osteoinductive composition comprising 1-methyl-2-pyrrolidone, and at least one bone morphogenetic protein, along with a porous glass ceramic, such as bioglass (current application, claims 1, 7, 8, 9, 10, and 25-35).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the

application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

18. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al (US 6,180,606 B1) in view of Weber, F. (US 2004/0152627 A1).

Chen et al. disclose a composition comprising an osteogenic composition having enhanced osteogenic potential, the composition comprising a porous or semi-porous matrix; at least one osteoinductive factor; and, at least one growth factor, nutrient factor, drug, calcium-containing compound, anti-inflammatory agent, antimicrobial agent, blood product, large molecular weight protein, or combination thereof present on or within the porous or semi-porous matrix or present on or within the osteoinductive factor. The composition further comprises calcium phosphate. The osteoinductive factor comprises bone morphogenetic proteins (see claims 1, 21, and 23). Chen et al. do not disclose a composition comprising a pyrrolidone that is selected from the group consisting of 1-methyl-2-pyrrolidone, 1-ethyl-2-pyrrolidone, 2-pyrrolidone and 1-cyclohexyl-2-pyrrolidone.

Weber, F. discloses a pharmaceutical composition comprising a bone morphogenetic protein and a pyrrolidone in a pharmaceutically acceptable carrier, wherein said bone morphogenetic protein and said pyrrolidone are present in an amount sufficient to provide a

synergetic therapeutic effect on bone formation. The pyrrolidone can comprise 1-methyl-2-pyrrolidone (see claims 1, and 3).

A person having ordinary skill in the art would have been motivated to use the pyrrolidone containing composition disclosed by Weber, F. with the calcium phosphate containing composition disclosed by Chen et al., because of the synergistic therapeutic effect on bone formation as disclosed by Weber, F. A person having ordinary skill in the art would have expected to succeed in using a composition comprising calcium phosphate, 1-methyl-2-pyrrolidone, and bone morphogenetic protein, because each material has been used for induction of bone formation. Therefore, it would have been obvious to the person having ordinary skill in the art to manufacture an osteoinductive composition comprising calcium phosphate, 1-methyl-2-pyrrolidone, and at least one bone morphogenetic protein (current application, claim 14).

Conclusion

19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

March 3, 2006

JON WEBER
SUPERVISORY PATENT EXAMINER